

1/11

FIG. 1

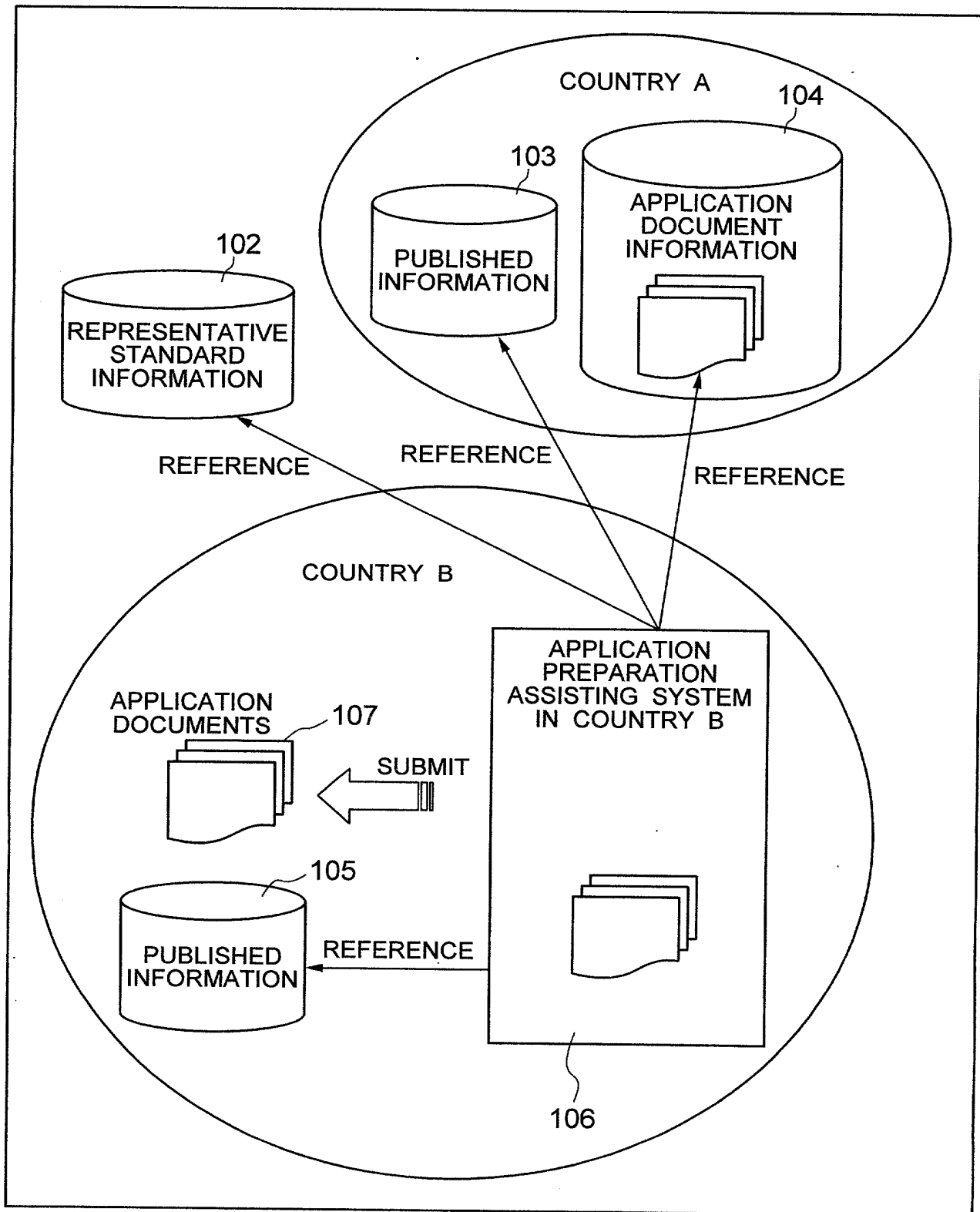
GENERAL CONFIGURATION OF APPLICATION
PREPARATION ASSISTING SYSTEM

FIG. 2

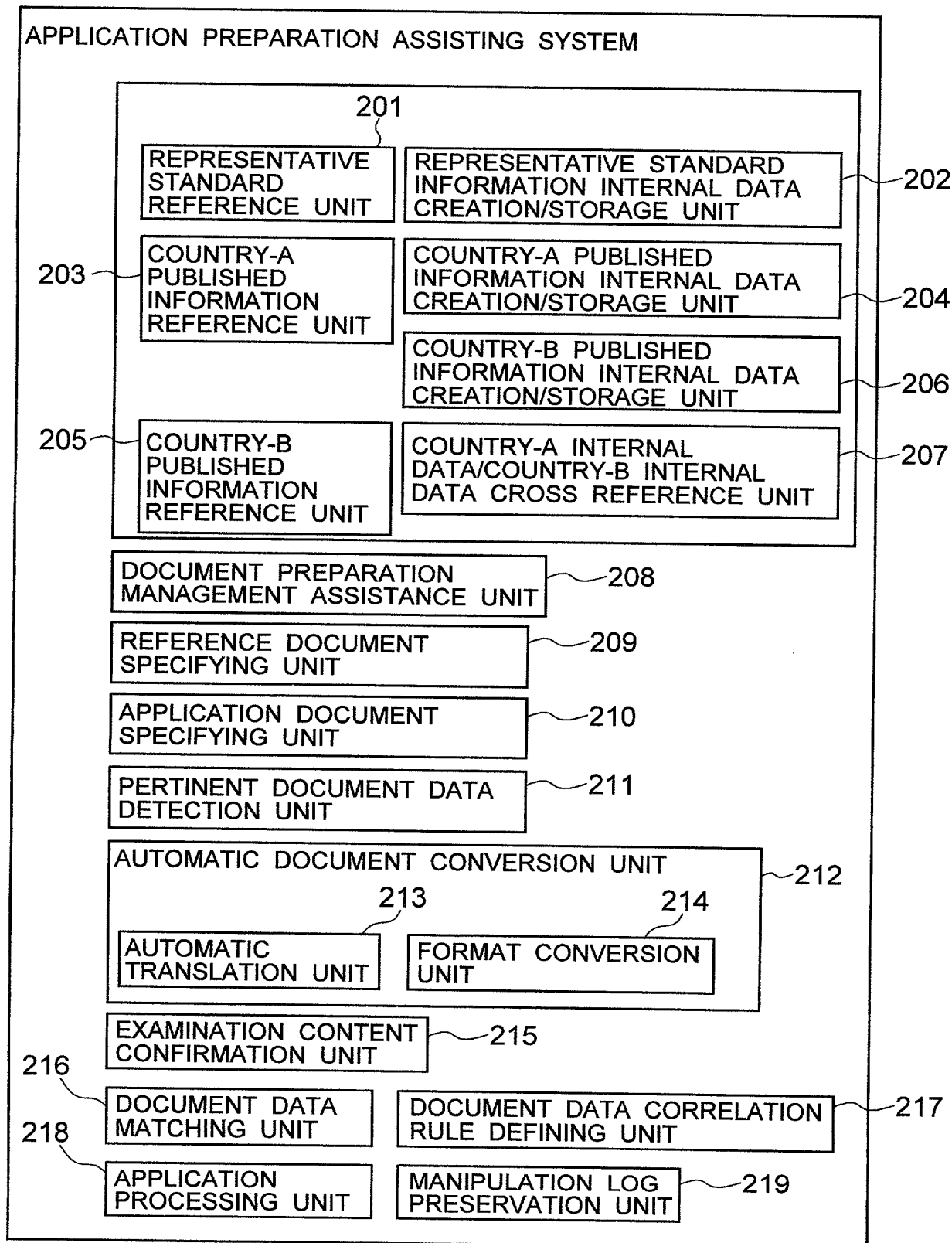
CONFIGURATION OF APPLICATION PREPARATION
ASSISTING SYSTEM

FIG. 3

EXAMPLE OF REFERENCE DOCUMENT
SPECIFYING SCREEN

301

EXAMPLE OF REFERENCE DOCUMENT SPECIFYING SCREEN

☐ NEW PREPARATION

☒ SELECT AN APPLICATION FOR REFERENCE FROM THE FOLLOWINGS WHEN ALREADY PERMITTED.

PERMITTING COUNTRY 302

PRODUCT NAME 303

OTHER SEARCH KEYWORD 304

↓

DOCUMENTS FOUND BY SEARCH : 305

√ DOCUMENT No. XXX ON GASTROINTESTINAL DRUG ALPHA PERMITTED IN COUNTRY A 306

OK CANCEL

FIG. 4

EXAMPLE OF SCREEN FOR CONVERTING REFERENCE
DOCUMENT TO DOCUMENT CONFORMING TO COUNTRY
TO BE APPLIED

400

SCREEN FOR SPECIFYING CONVERSION TO COUNTRY OF INTEREST

SELECT COUNTRY TO WHICH NEW APPLICATION IS
MADE, AND APPLICATION METHOD

COUNTRY TO
BE APPLIED

COUNTRY B



401

USE

COMMERCIALY
AVAILABLE DRUG



402

SHAPE OF
DRUG

CAPSULE



403

COMPONENT

WITHOUT
ADJUSTMENT



404



405

WITHIN DOCUMENTS REQUIRED FOR APPLICATION,
DATA EXISTS CORRESPONDING TO DOCUMENTS
MARKED WITH SHADED SQUARE.
DO YOU SELECT AUTOMATIC CONVERSION ?

406 ☒ APPLICATION 1 ☐ APPLICATION 2 ☐ APPLICATION 3
☐ APPLICATION 4 ☒ APPLICATION 5 ☐ APPLICATION 6
☒ APPLICATION 7 ☒ APPLICATION 8 ☒ APPLICATION 9

407

AUTOMATIC
CONVERSION

EDIT
DOCUMENT

408

FIG. 5

FLOW OF PROCESSING FOR CONVERTING REFERENCE
DOCUMENT TO DOCUMENT CONFORMING TO COUNTRY
TO WHICH APPLICATION IS MADE

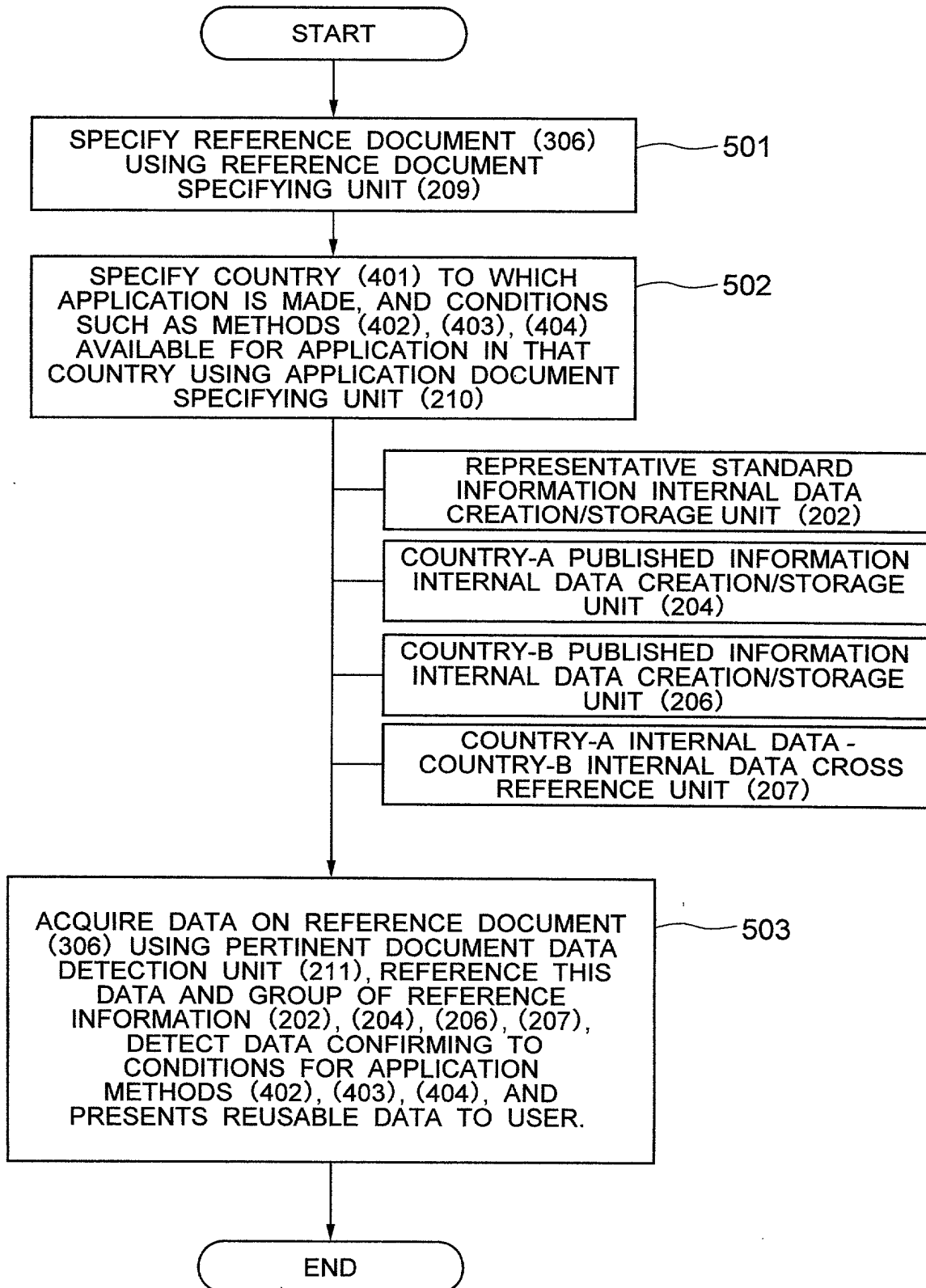


FIG. 6

EXAMPLE OF SCREEN WHEN AUTOMATIC
CONVERSION IS INSTRUCTED

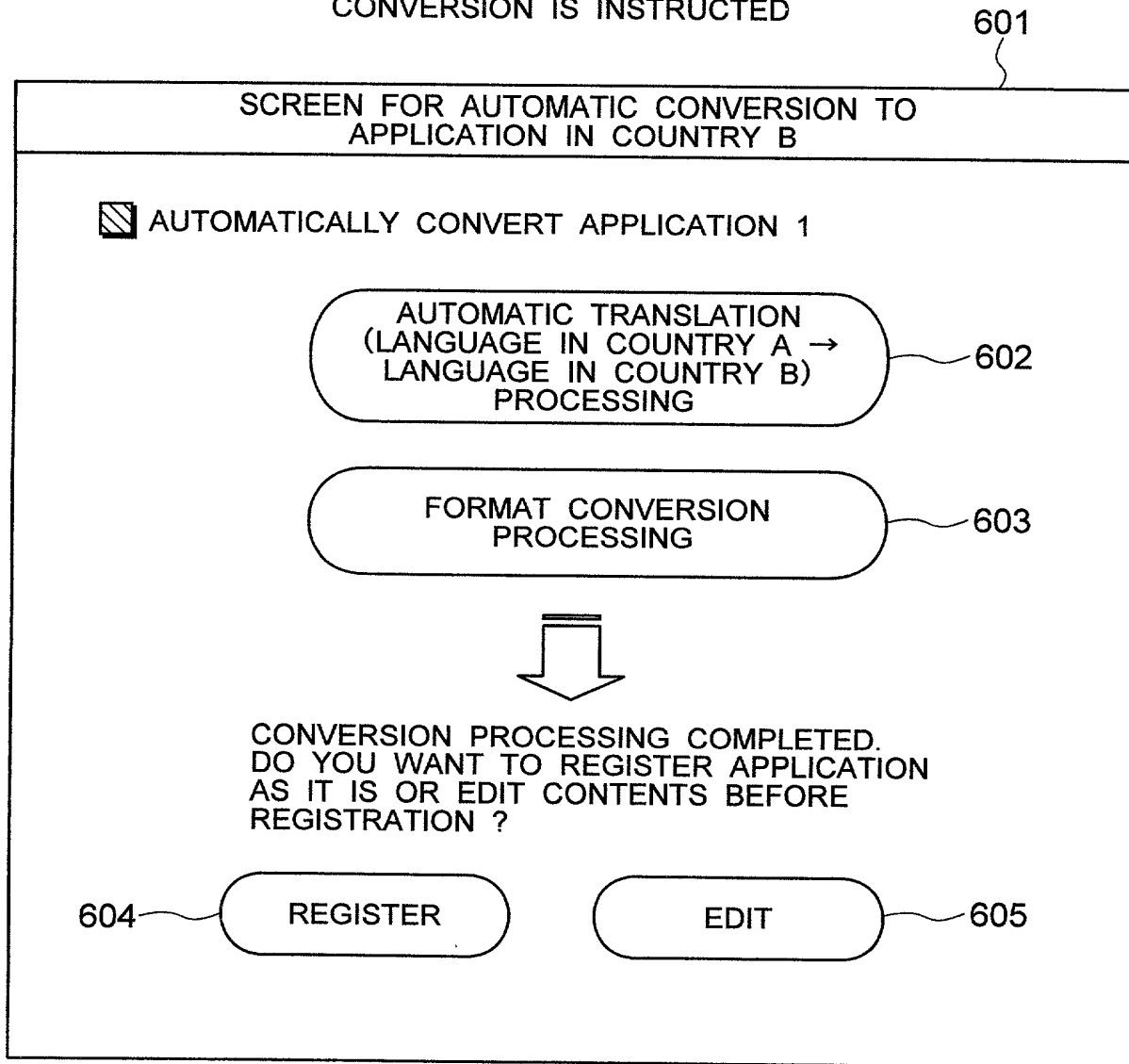


FIG. 7

EXAMPLE OF POST-PREPARATION
CONFIRMATION SCREEN

701

APPLICATION PROCESSING CONFIRMATION SCREEN

DOCUMENTS APPLIED TO COUNTRY B HAVE BEEN PREPARED.
DO YOU WANT TO CONFIRM EXAMINATION CONTENTS ?

<input type="checkbox"/> APPLICATION 1	<input type="checkbox"/> APPLICATION 2	<input type="checkbox"/> APPLICATION 3
<input type="checkbox"/> APPLICATION 4	<input type="checkbox"/> APPLICATION 5	<input type="checkbox"/> APPLICATION 6
<input type="checkbox"/> APPLICATION 7	<input type="checkbox"/> APPLICATION 8	<input type="checkbox"/> APPLICATION 9

702 CONFIRM 703 PRESERVE

704

APPLICATION 1 INCLUDES IMPROPER EXPRESSION
CONTENTS: DRUG COMPONENT α 1% \rightarrow
APPLICATION = EXAMINATION CRITERIA ON
COMMERCIALY AVAILABLE DRUG:
DRUG COMPONENT α SHALL BE 0.5% OR LESS

705 CHANGE DESCRIBED CONTENTS TO
COMPLY DATA TO EXAMINATION
CRITERIA.

FIG. 8

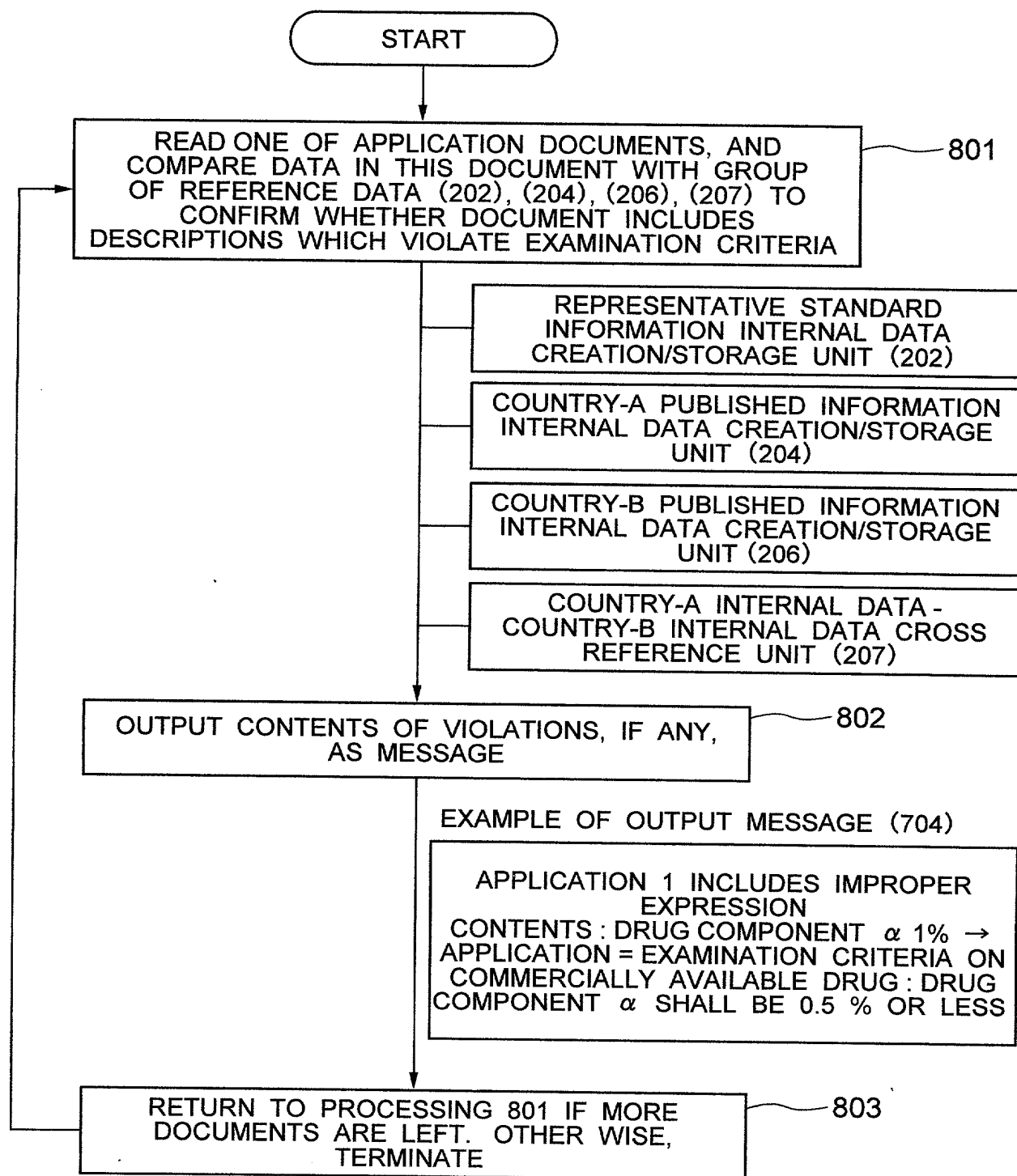
PROCESSING FLOW OF EXAMINATION
CONTENT CONFIRMATION UNIT (215)

FIG. 9

EXAMPLE OF DATA MATCHING SCREEN


901

DATA MATCHING SCREEN

APPLICATION 1 INCLUDES IMPROPER EXPRESSION
 CONTENTS : DRUG COMPONENT α 1% \rightarrow EXAMINATION
 CRITERIA : DRUG COMPONENT α SHALL BE 0.5 % OR LESS

903 FOR CHANGING
 COMPONENT, ASSOCIATED
 DATA = <CLINICAL DATA>
 MUST BE CHANGED.
 DO YOU WANT TO
 CHANGE ?

CHANGE

904 

SELECT ASSOCIATED DATA
 FOR REPLACEMENT

DRUG COMPONENT α 1 %
 DRUG COMPONENT α 0.8 %
 ✓ DRUG COMPONENT α 0.5 %
 DRUG COMPONENT α 0.1 %
 DRUG COMPONENT α 0.08 mg

REPLACE

902

<APPLICATION 1>
 <COMPONENTS>
 DRUG COMPONENT α 1 % ;
 β -CISTRON 0.025 % ;
 DRUG COMPONENT γ 0.08 mg
 </COMPONENT>
 <EFFECT>
 ANTIPHLOGISTIC ACTION ON
 INNER WALLS OF STOMACH AND
 INTESTINE </EFFECT>
 <DOSAGE>
 ADULTS (15 YEAR-OLD OR MORE) :
 TAKE ONE CAPSULE AFTER EVERY
 MEAL, CHILDREN (15-YEAR-OLD OR
 LESS) TAKE ONE CAPSULE A DAY
 </DOSAGE>
 <SIDE EFFECT>
 LOSS OF APPETITE </SIDE EFFECT>
 <CLINICAL DATA>
 DATA ID - XXIIILLL
 COMPONENT : DRUG COMPONENT α
 1 % ; β -CISTRON 0.025 % ; DRUG
 COMPONENT γ 0.08 mg
 :
 </CLINICAL DATA>
 </APPLICATION 1>

905 PRESERVE APPLICATION 1
 AFTER REPLACEMENT

906 CANCEL

FIG. 10

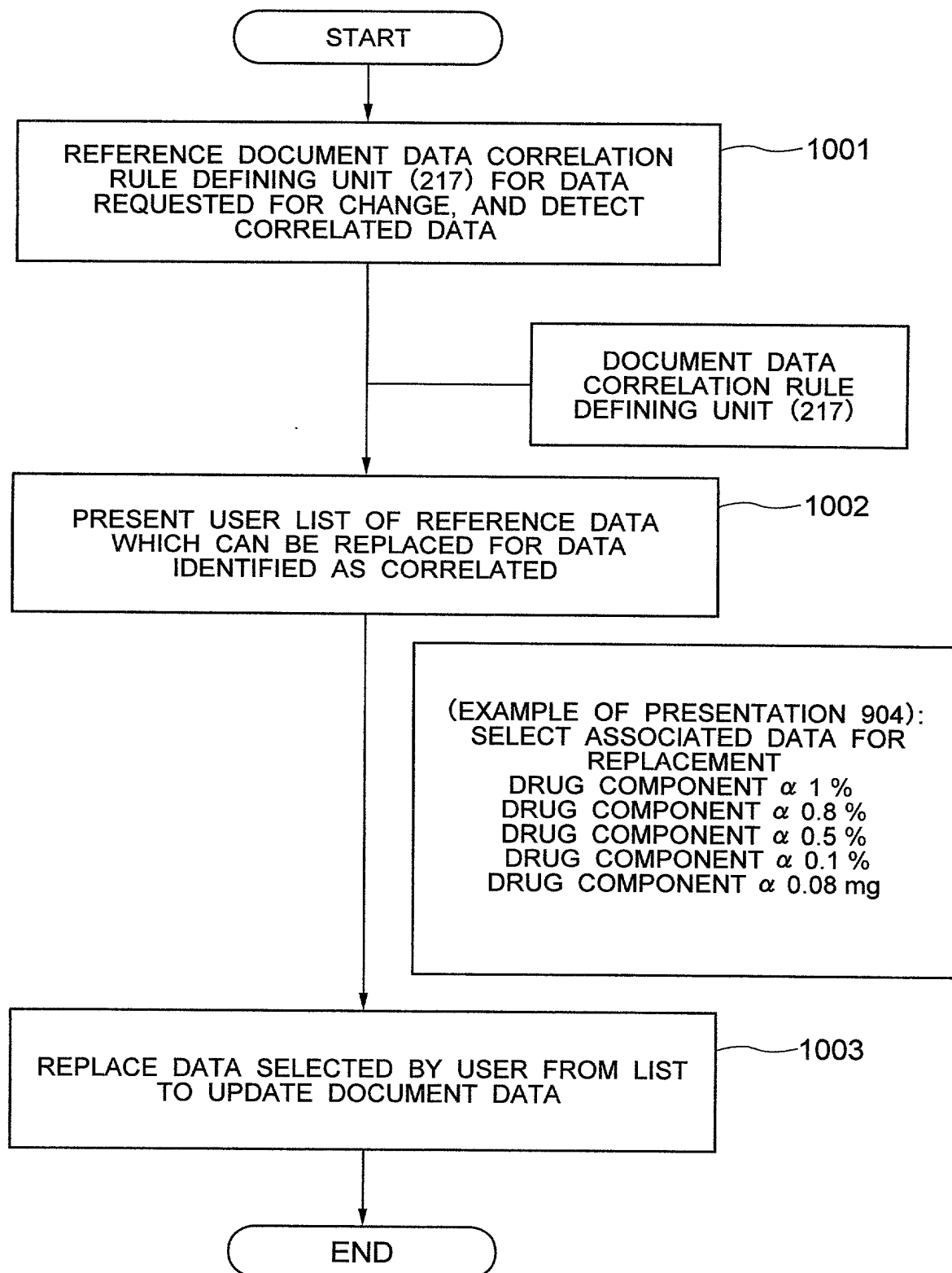
PROCESSING FLOW IN DOCUMENT
MATCHING UNIT (216)

FIG. 11

EXAMPLE OF APPLICATION
SUBMISSION SCREEN

1101

APPLICATION SUBMISSION SCREEN

EXAMINATION CONTENTS HAVE BEEN CONFIRMED FOR ALL
DOCUMENTS. DO YOU WANT TO SUBMIT DOCUMENTS TO
INTENDED COUNTRY ?

- | | | |
|--|--|--|
| <input type="checkbox"/> APPLICATION 1 | <input type="checkbox"/> APPLICATION 2 | <input type="checkbox"/> APPLICATION 3 |
| <input type="checkbox"/> APPLICATION 4 | <input type="checkbox"/> APPLICATION 5 | <input type="checkbox"/> APPLICATION 6 |
| <input type="checkbox"/> APPLICATION 7 | <input type="checkbox"/> APPLICATION 8 | <input type="checkbox"/> APPLICATION 9 |

SUBMIT

CANCEL



1102

SUBMISSION PROCESSING REQUEST HAS BEEN TRANSMITTED.

REQUEST TIME : XX:YY:ZZ IN STANDARD TIME OF COUNTRY B

(INTERNATIONAL STANDARD TIME = Date)

SUBMITTED DOCUMENTS AND SUBMISSION INFORMATION ARE
PRESERVED BEFORE TERMINATION

STORAGE FILE : DOCUMENT ID = XXXIILLLLKKKK

PRODUCT NAME : GASTROINTESTINAL DRUG α